

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Can V. BUI and Cuong Q. BUI

Group Art Unit: 1654

Serial Number: 10/560,558

Examiner: Not Yet Assigned

Filing Date: December 12, 2005

**CONFIRMATION NO: 2816**

Title: Nutraceutical for the prevention and  
treatment of cancers and diseases affecting  
the liver

Certificate of Electronic Filing

I hereby certify that the attached Information Disclosure Statement and all marked attachments are being deposited by Electronic Filing on January 9, 2007 by using the EFS – Web patent filing system and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Ann Lygas  
Ann Lygas

Date: January 9, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.97**

Sir:

Applicant hereby submits an Information Disclosure Statement along with attached forms PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant respectfully requests that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant further requests that the Examiner initial and return the attached forms PTO/SB/08 in accordance with MPEP §609.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

A.  37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

(1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);  
-- OR --

(2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;  
-- OR --

(3) It is being filed before the mailing of a first Office action on the merits;  
-- OR --

(4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

B.  37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

a statement as specified in §1.97(e) provided concurrently herewith;  
-- OR --

a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C.  37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in §1.97(e);  
-- AND --

ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D.  37 CFR §1.97(e). Statement.

A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);  
-- AND/OR --

A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);  
-- AND/OR --

A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.

E.  Statement Under 37 C.F.R. §1.704(d). Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F.  37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G.  37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: \_\_\_\_\_

Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H.  37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: \_\_\_\_\_

Information Disclosure Statement(s) filed on: \_\_\_\_\_

AND

The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I.  *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.30915-701.831).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: Jan. 8, 2007

By: Vicki G. Norton  
Vicki G. Norton  
Reg. No. 40.745

650 Page Mill Road  
Palo Alto, CA 94304-1050  
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Customer No. 021971

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<p>Substitute for form 1449/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p><i>(Use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	10/560,558
				Filing Date	December 12, 2005
				First Named Inventor	Can V. BUI
				Art Unit	1654
Examiner Name	Not Yet Assigned				
Sheet	1	Of	8	Attorney Docket Number	30915-701.831

<b>NON PATENT LITERATURE DOCUMENTS</b>				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	1.	AGUAYO, Alvaro and PATT, Yehuda Z., "Liver Cancer," Clinics in Liver Disease Vol 5(2):479-507 (2001)		
	2.	AGUAYO, Alvaro and PATT, Yehuda Z., "Liver Tumors: Nonsurgical Treatment of Hepatocellular Carcinoma," Clinics in Liver Disease Vol 5 (1):175-189 (2001)		
	3.	ARASE, Yasuji et al., "The Long Term Efficacy of Glycyrrhizin in Chronic Hepatitis C Patients," Cancer Vol. 79 (8): 1494-1500 (1997)		
	4.	BARNETT, JR., Carlton C. and CURLEY, Steven A., "Ablative Techniques for Hepatocellular Carcinoma," Seminars in Oncology Vol 28(5):487-496 (2001)		
	5.	CARR, Brian I. et al., K Vitamins, PTP Antagonism, and Cell Growth Arrest," J. Cell. Physiol. 193:263-274 (2002)		
	6.	CORSI, M.M. et al., "The Therapeutic Potential of Aloe Vera in Tumor-Bearing Rats," Tissue Reactions XX(4):115-118 (1998)		
	7.	DRAGNEV, Konstantin H. et al., "The Retinoids and Cancer Prevention Mechanisms," The Oncologist 5:361-368 (2000)		
	8.	FENECH, M., "Micronutrients and genomic stability: a new paradigm for recommended dietary allowances (RDAs)," Food and Chemical Toxicology 40:1113-		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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		1117 (2002)			
	9.	FENECH, Michael, "Recommended dietary allowances (RDAs) for genomic stability," Mutation Research 480-481:51-54 (2001)			
	10.	GEORGIADES, Christos S. et al., "New Nonsurgical Therapies in the Treatment of Hepatocellular Carcinoma," Techniques in Vascular and Interventional Radiology 4(3):193-199 (2001)			
	11.	GIOVANNINI, M. et al., "Hepatocellular carcinoma," Br. J. Cancer 84(Suppl.2):74-77 (2001)			
	12.	HE, Youping et al., Effects of Carotenoid-Rich Food Extracts on the Development of Preneoplastic Lesions in Rat Liver and on In Vivo and In Vitro Antioxidant Status," Nutrition and Cancer 27(3):238-244 (1997)			
	13.	KANG, Jiu-Hong et al., "Effects of ascorbic acid and DL- $\alpha$ -tocopherol on humanhepatoma cell proliferation and redifferentiation," Acta Pharmacol. Sin. 21(4):348-352 (2000)			
	14.	KANG, Jiu-Hong et al., "Effects of ascorbic acid on human hepatoma cell proliferation and redifferentiation," Acta Pharmacol. Sin. 20(11):1019-1024 (1999)			
	15.	KASHEF, Elika and ROBERTS, John P., "Transplantation for Hepatocellular			

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		Carcinoma," Seminars in Oncology 28(5):497-502 (2001)		
	16.	KEW, M.C., "Hepatitis viruses and hepatocellular carcinoma," Res. Virol. 149:257-262 (1998)		
	17.	KUO, Po-Lin et al., "The antiproliferative activity of aloe-emodin is through p53-dependent and p21-dependent apoptotic pathway in human hepatoma cell lines," Life Sciences 71:1879-1892 (2002)		
	18.	KUYVENHOVEN, J. Ph. Et al., "Practical Management of Hepatocellular Carcinoma," Scand. J. Gastroenterol. Suppl 234:82-87 (2001)		
	19.	LEE, Simon Ming Yuen et al., "Paeoniae Radix, a Chinese herbal extract, inhibit hepatoma cells growth by inducing apoptosis in a p53 independent pathway," Life Sciences 72:2267-2277 (2002)		
	20.	LEE, Kwang Youl et al., "Aloesin up-regulates cyclin E/CDK2 kinase activity via inducing the protein levels of cyclin E, CDK2, and CDC25A in SK-HEP-1 cells," Biochem. and Mol. Biol. International 41(2):285-292 (1997)		
	21.	LEUNG, Thomas W.T. and JOHNSON, Philip J., "Systemic Therapy for Hepatocellular Carcinoma," Seminars in Oncology 28(5):514-520 (2001)		
	22.	LITTLE, Sarah A. and FONG, Yuman, "Hepatocellular Carcinoma: Current Surgical		

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		Management," Seminars in Oncology 28(5):474-486 (2001)			
	23.	MEYSKENS, Frank L. et al., "Phase II trial of oral $\beta$ -all trans-retinoic acid in hepatocellular carcinoma (SWOG 9157)," Investigational New Drugs 16:171-173 (1998)			
	24.	MORADPOUR, Darius et al, "Hepatitis C: an update," Swiss Med. Wkly. 131:291-298 (2001)			
	25.	MORADPOUR, D. et al., Hepatitis C: A concise review," Minerva Med. 92:329-339 (2001)			
	26.	MORIWAKI, Hisataka et al., "Nutritional pharmacotherapy of chronic liver disease: from support of liver failure to prevention of liver cancer," J. Gastroenterol. 35(Suppl XII):13-17 (2000)			
	27.	MUTO, Yasutoshi et al., "Prevention of second primary tumors by an acyclic retinoid, polyprenoic acid, in patients with hepatocellular carcinoma," New England J. of Med. 334(24):1561-1567 (1996)			
	28.	NACCARATO, R. and FARINATI, F., "Hepatocellular Carcinoma, Alcohol, and Cirrhosis: Facts and Hypotheses," Digestive Diseases and Sciences 36(8):1137-1142 (1991)			

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	29.	NAKAMURA, Noriaki et al., "Apoptosis in Human Hepatoma Cell Line Induced by 4,5-Didehydrogeranylgeranoic Acid (Acyclic Retinoid) via Down-Regulation of Transforming Growth Factor- $\alpha$ ," Biochem. and Biophys. Res. Comm. 219:100-104 (1996)			
	30.	NI, Runshou et al., "Cell Growth Inhibition by a Novel Vitamin K Is Associated with Induction of Protein Tyrosine Phosphorylation," J. of Biol. Chem. 273(16):9906-9911 (1998)			
	31.	NISHIKAWA, Yuji et al., "Inhibition of Hepatoma Cell Growth in Vitro by Arylating and Non-arylating K Vitamin Analogs," J. of Biol. Chem. 274(49):34803-34810 (1999)			
	32.	NISHIKAWA, Yuji et al., "Growth Inhibition of Hepatoma Cells Induced by Vitamin K and Its Analogs," J. of Biol. Chem. 270(47):28304-28310 (1995)			
	33.	OKUNO, Masataka et al., "Chemoprevention of hepatocellular carcinoma: Concept, progress and perspectives," J. Gastroenterol. And Hepatol. 16:1329-1335 (2001)			
	34.	PUATANACHOKCHAI, Rawiwan et al., "Inhibitory effects of lemon grass (Cymbopogon citratus, Stapf) extract on the early phase of hepatocarcinogenesis after initiation with diethylnitrosamine in male Fischer 344 rats," Cancer Letters 183:9-15 (2002)			
	35.	RIEDER, A. et al., "Delay of Diethylnitrosamine-Induced Hepatoma in Rats by Carrot			

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		Feeding," Oncology 40:120-123 (1983)		
	36.	ROSS, Ronald K. et al., "Urinary aflatoxin biomarkers and risk of hepatocellular carcinoma," The Lancet 339 (8799):943-946 (1992)		
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Sheet	7	Of	8	Application Number	10/560,558
				Filing Date	December 12, 2005
				First Named Inventor	Can V. BUI
				Art Unit	1654
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	30915-701.831

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
		Rat Liver Epithelial Cells In Vitro," J Cell. Physiol. 175:30-40 (1998)	
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		57(4): 265- 269 (2002)			
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